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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,483

09/23/2003

Takumi Kagawa

380-41

9078

23117

7590

07/25/2006

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

PERLINGER, SARAH E

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/667,483	Applicant(s) KAGAWA ET AL.	
	Examiner Sarah E. Perlinger	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-14 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/06/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 9-14 and 26-30 are pending. Claims 1-8 and 15-25 have been canceled in the preliminary amendment filed May 11, 2006. Claims 12-14 and 26-30 are drawn to non-elected inventions and are therefore withdrawn from consideration.

2. ***Claim Rejections - 35 USC § 112***

Applicant's arguments with regard to the 112 first paragraph rejection against claims 9-11, filed May 11, 2006 have been fully considered but they are not persuasive. As stated in the previous office action, the specification contains a description of the (2S,3R)-stereoisomer (see Specification, pages 16-17), however no description can be found for (2S,3S), (2R,3S) or (2R,3R) stereoisomers of the instant claimed compound of formula (3). Applicant's argument that the (2R,3S) form is described on page 41, lines 6-11 is not persuasive because the description on page 41 is drawn to a process of making (2R,3S)-2,3-epoxy-3-cyclohexylpropionic acid which is a compound of formula (4), not the instant claimed compound of formula (3). Upon review of the specification, description of the (2R,3S), (2S,3S) or (2R,3R) stereoisomers of the compound of formula (3) could not be found and therefore the rejection under 112 first paragraph is maintained.

3. ***Claim Rejections - 35 USC § 102***

The amendment to instant claim 9 and Applicant's arguments, (see page 7 of the Response, filed May 11, 2006) with respect to Corey et al. *Tetrahedron Letters* 102(b) rejection have been fully considered and are persuasive. The 102(b) rejection of claims 9-11 has been withdrawn.

4. ***Claim Rejections - 35 USC § 103***

In view of the amendment of claim 9, filed May 11, 2006, the rejection of claims 9-11 under 35 U.S.C. 103(a) has been withdrawn.

5. ***Double Patenting***

Applicants stated that a response to the rejection of claims 9 and 11 on the grounds of non-statutory obviousness-type double patenting over claims 1-2 of U.S. 6,787,657 is held in abeyance until such time as allowable subject matter is indicated in this application and the final form of allowable claims is reached. Therefore, the rejection of claims 9 and 11 over claims 1-2 of US 6,787,657 is maintained.

The following rejection is necessitated by applicants' amendment to the claims filed on May 11, 2006:

6. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Upon review of the specification, no description of a (2R,3S) form of the compound of formula (3) could be found. In the response filed May 11, 2006, Applicants refer to lines 6-11 of page 41 for description of the (2R,3S) form of the instant claimed compound of formula (3). Lines 6-11 of page 41 however, provide written description for a carboxylic acid compound of formula (4) not for the (2R,3S) form of the compound of formula (3). The amendment of claims 9-11 represents NEW MATTER. This is a NEW MATTER rejection. Removal of the new matter is required see *In re Rasmussen*, 211 USPQ 323.

7. Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the (2S,3R) form of the instant claimed compound of formula (3), does not reasonably provide enablement for making the (2R,3S) form of the instant claimed compound of formula (3)(see Specification, pages 16-17). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Nature of Invention

The instant claims are drawn to an optically active epoxyester derivative in the (2S,3R) or (2R,3S) form of formula (3).

The State of the Art and Predictability

Unlike the mechanical art, the high degree of unpredictability is well recognized in the chemical synthetic art. A change in the structure of the compound may drastically affect the rate of the chemical reaction.

The Amount of Guidance and Working Examples

The starting materials of claims 9-11 with regard to the synthesis of the (2R, 3S) form of the compound of formula (3) were not provided in the specification. Furthermore, no reference to making the (2R, 3S) form of the compound of formula (3) could be found (see Specification, pages 16-17). Absent sources, the public is offered mere language, rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarthe 210 USPQ 689.

Amount of Undue Experimentation

Since insufficient teaching and guidance are provided by the specification, one of ordinary skill in the art, even with a high degree of skill, would not be able to make the (2R, 3S) form of the compound of formula (3).

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. **Conclusion**

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Thomas McKenzie, can be reached at (571) 272-0670. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AP

07/11/2006



Celia Chang
Primary Examiner
Art Unit 1625